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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,250	09/25/2003	Leland Shapiro	330310.00103	3190

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/669,250	<b>Applicant(s)</b> SHAPIRO, LELAND	
	<b>Examiner</b> Kevin E. Weddington	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2-8-05</u> . | 6) <input type="checkbox"/> Other: _____  |

Claims 31-33 are presented for examination.

Applicants' drawings filed September 25, 2003; preliminary amendment filed July 30, 2004; and the information disclosure statement filed February 8, 2005 have been received and entered.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 31 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/427,929. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of sparing tissue levels of  $\alpha$ 1-antitrypsin in an animal, comprising administering a nitric oxide synthase inhibitor; and the copending application

teach a method of treating an animal suffering from a pathological condition, comprising administering at least one agent where the agent suppresses nitric oxide synthesis and exhibits mammalian  $\alpha$ 1-antitrypsin,  $\alpha$ 1-antitrypsin-like, elastase inhibitory, or proteinase-3-inhibitory activity. Note the pathological condition in the copending application are caused by reduced  $\alpha$ 1-antitrypsin activity, thus levels of  $\alpha$ 1-antitrypsin in the tissue are spared by the agents that suppresses nitric oxide synthesis (nitric oxide inhibitor). Clearly, present application' method is inherent by the action or method of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 31 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 25 of copending Application No. 10/669,251. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of sparing tissue levels of  $\alpha$ 1-antitrypsin in an animal, comprising administering a nitric oxide synthase inhibitor; and the copending application teaches a method of treating ischemia reperfusion injury, comprising administering at least one  $\alpha$ 1-antitrypsin-like agent (AAT). Note the ischemia reperfusion injury is a pathological condition caused by reduced  $\alpha$ 1-antitrypsin activity, thus the levels of  $\alpha$ 1-antitrypsin in the tissues are spared by the agent wherein a nitric oxide synthase inhibitor also exhibits  $\alpha$ 1-antitrypsin-like activity (see applicants' specification of

10/669,251). Clearly, the present application's method is inherent by the action or method of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 31 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18 and 19 of copending Application No. 10/669,441. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application teaches a method of inhibiting nitric oxide production in a cell susceptible to producing nitric oxide, which comprises contacting the cell with a composition comprising at least one agent exhibiting mammalian  $\alpha$ 1-antitrypsin,  $\alpha$ 1-antitrypsin-like, or serine protease inhibitor activity; and the present application teach a method of sparing tissue levels of  $\alpha$ 1-antitrypsin in an animal, comprising administering a nitric oxide synthase inhibitor. Note the copending application's mechanism anticipates the present application's mechanism.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kolb et al., "Suppression of low dose streptozotocin induced diabetes in mice by administration of a nitric oxide synthase inhibitor", Life Sciences, 1991, Vol. 49, No. 25, pp. PL213-PL217 or Pizcutea et al., "Modulation of the hyperdynamic circulation of cirrhotic rats by nitric oxide inhibition", Gastroenterology, 1992, Vol. 103, No. 6, pp. 1909-1915.

Kolb et al. teach the administration of a nitric oxide synthase inhibitor, N-nitro-L-argininemethylester (NAME) to treat diabetes (see the abstract).

Pizcutea et al. teach the administration of NG-monomethyl-L-arginine (L-NMMA), an inhibitor of nitric oxide, to treat cirrhosis and hypertension in rats (see the abstract).

Note the two primary references, each individually, teach the administration of a nitric oxide synthase inhibitor to treat diseases or disorders resulted from reduced  $\alpha$ 1-antitrypsin activity as described in applicants' specification on page 19, lines 14-31 and page 20, lines 1-5. Inherently, the levels of  $\alpha$ 1-antitrypsin in the tissue are spared by inhibitors that suppress nitric oxide synthesis (nitric oxide inhibitor) since the inhibitors are known to possess  $\alpha$ 1-antitrypsin activity. Clearly, the cited references, each individually, anticipate the applicants' instant invention; therefore, the instant invention is unpatentable.

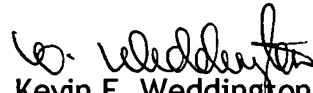
Claims 31-33 are not allowed.

The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington  
January 3, 2006